



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

ORO Agri, Inc.
990 Trophy Club Drive
Trophy Club, TX 76262

EPA File Symbol/Registration Number

72662-

Product Name

Prev-Gard

Date of Confidential Statement of Formula (EPA Form 8570-4)

September 14, 2004

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Sodium Tetraborohydrate Decahydrate

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Sodium Tetraborohydrate Decahydrate	[REDACTED]	[REDACTED]
<p>Signature: <i>James Sullivan</i></p> <p>Name and Title: James Sullivan/Chief Financial Officer</p> <p>Date: SEP 14, 2004</p>		

EPA Form 8570-27 (Rev. 8-95)

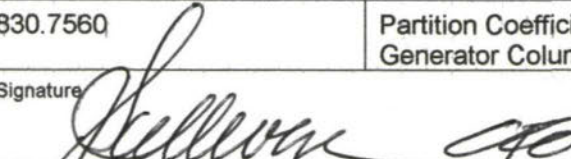
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DATA MATRIX

Date September 14, 2004	EPA Reg No./File Symbol 72662-	Page of 3
Applicant's/Registrant's Name & Address ORO Agri, Inc. 990 Trophy Club Drive Trophy Club, TX 76262		Product PREV-Gard

Ingredient Pronamide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility				Not required ⁵
830.6317	Storage Stability				PRN 92-5 ⁶
830.6319	Miscibility				Not required ⁷
830.6320	Corrosion Characteristics				See endnote ⁶
830.6321	Dielectric Breakdown Voltage				Not required ⁸
830.7000	pH	See 72662-2 (self certification)	ORO Agri, Inc.	OWN	
830.7050	UV/Visible Absorption				Not required ³
830.7100	Viscosity	See 72662-2 (self certification)	ORO Agri, Inc.	OWN	
830.7200	Melting Point/Melting Range				Not required ³
830.7220	Boiling Point/Boiling Range				Not required ³
830.7300	Density/Relative Density/Bulk Density	See 72662-2 (self certification)	ORO Agri, Inc.	OWN	
830.7370	Dissociation Constants in Water				Not required ³
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ³
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				Not required ³
Signature 			Name and Title James Sullivan; Chief Financial Officer		Date SEP 14, 2004

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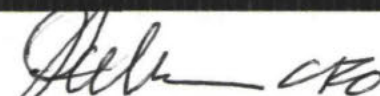
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Ingredient **Sodium tetraborohydrate decahydrate**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required ⁵
					PRN 92-5 ⁶
					Not required ⁷
					See endnote ⁶
					Not required ⁸
			ORO Agri, Inc.	OWN	
					Not required ³
			ORO Agri, Inc.	OWN	
					Not required ³
					Not required ³
			ORO Agri, Inc.	OWN	
					Not required ³
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Signature 			Name and Title James Sullivan; Chief Financial Officer	Date SEP 14, 2004	

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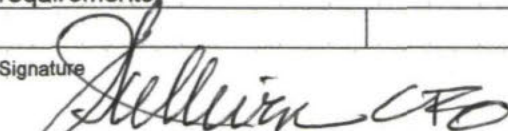
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Ingredient **Pronamide**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				Not required ³
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ³
830.7860	Water Solubility, Generator Column Method				Not required ³
830.7950	Vapor Pressure				Not required ³
870.1100	Acute Oral Toxicity: Rat	45276502	ORO Agri, Inc.	OWN	
870.1200	Acute Dermal Toxicity: Rat	45276503	ORO Agri, Inc.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	45075503	ORO Agri, Inc.	OWN	
870.2400	Primary Eye Irritation: Rabbit	45276504	ORO Agri, Inc.	OWN	
870.2500	Primary Dermal Irritation	45276505	ORO Agri, Inc.	OWN	
870.2600	Dermal Sensitization	45075506	ORO Agri, Inc.	OWN	

Sodium Tetraborohydrate Decahydrate Generic Data Requirements

ORO Agri, Inc. qualifies for Formulator's Exemption for all generic data requirements

Signature 	Name and Title James Sullivan, Chief Financial Officer	Date SEP 14, 2004
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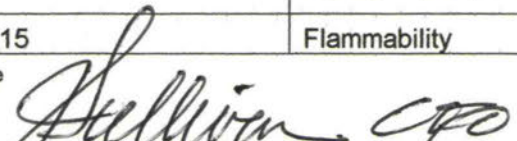
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Ingredient Sodium tetraborohydrate decahydrate					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required ³
					Not required ³
					Not required ³
					Not required ³
			ORO Agri, Inc.	OWN	
			ORO Agri, Inc.	OWN	
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Ingredient Pronamide					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	45924701	ORO Agri, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	45924701	ORO Agri, Inc.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	45924701	ORO Agri, Inc.	OWN	
830.1670	Discussion of Formation of Impurities	45924701	ORO Agri, Inc.	OWN	
830.1700	Preliminary Analysis				Not required ²
830.1750	Certified Limits	45924701	ORO Agri, Inc.	OWN	
830.1800	Enforcement Analytical Method	45924701	ORO Agri, Inc.	OWN	
830.6302	Color				Not required ³
830.6303	Physical State	See 72662-2 (self certification)	ORO Agri, Inc.	OWN	
830.6304	Odor				Not required ³
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility	See 72662-2 (self certification)	ORO Agri, Inc.	OWN	
830.6315	Flammability				Not required ⁴
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			ORO Agri, Inc.	OWN	
			ORO Agri, Inc.	OWN	
					Not required ¹
			ORO Agri, Inc.	OWN	
			ORO Agri, Inc.	OWN	
					Not required ²
			ORO Agri, Inc.	OWN	
			ORO Agri, Inc.	OWN	
					Not required ³
			ORO Agri, Inc.	OWN	
					Not required ³
					Not required ³
			ORO Agri, Inc.	OWN	
		Not required ⁴			
Signature			Name and Title James Sullivan; Chief Financial Officer		Date Sep 14, 2004

Endnotes for Data Matrix for PREV-Gard

- ¹ **830.1620** - Per OPPTS 830.1000, these data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** - This product does not consist solely of the technical grade active ingredient (TGA1) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6302, 830.6304, 830.6313, 830.7050, 830.7200, 830.7220, 830.7370, 830.7550, 830.7560, 830.7570, 830.7840, 830.7860 and 830.7950** - Per OPPTS 830.1000, these data are not required for the registration of a end-use product.
- ⁴ **830.6315** - This product is not a combustible liquid; therefore these data are not applicable to this end-use product. Please refer to the Confidential Statement of Formula for additional information on the composition of PREV-Gard.
- ⁵ **830.6316** - This product does not have explosive characteristics; therefore these data are not required. Please refer to the Confidential Statement of Formula for additional information on the composition of PREV-Gard.
- ⁶ **830.6317, 830.6320** - ORO Agri, Inc. is currently conducting storage stability and corrosion characteristic studies to satisfy guidelines 830.6317 and 830.6320, respectively. Per PR Notice 92-5, storage stability data are not required to be submitted unless specifically requested by the Agency. OPPTS 830.6317 and 830.6320 guidelines allow the corrosion characteristics study and storage stability study to be conducted simultaneously.
- ⁷ **830.6319** - PREV-Gard is a water based formulation and not an emulsifiable concentrate. In addition, the proposed label recommends dilution of PREV-Gard with water, not oil; therefore, these data are not applicable nor are these data required.
- ⁸ **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable nor are these required.



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